

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ni et al.

Docket No.: PF400D1C1D1

Application No.: Not Yet Assigned

Confirmation No.: Not Yet Assigned

Filed: Concurrently Herewith

Art Unit: N/A

For: Human IRAK-2

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of a claim of the subject application, Attorney for Applicants hereby directs the Examiner's attention to references A-CS listed on the attached Form PTO/SB/08.

A copy of reference A was submitted by Applicants or cited by the Examiner in connection with U.S. Application No. 08/980,060, filed November 26, 1997, now U.S. Patent No. 5,965,421, to which the instant application claims priority under 35 U.S.C. § 120. Copies of references B-CS were submitted by Applicants or cited by the Examiner in connection with U.S. Application No. 09/773,753, filed February 2, 2001, to which the instant application claims priority under 35 U.S.C. § 120. Pursuant to 37 C.F.R. § 1.98(d), the Examiner is directed to the file of U.S. Application Nos. 08/980,060 and 09/773,753 for copies of references A-CS.

The listed references are presented so that the Patent and Trademark Office can determine any materiality thereof to the claimed invention. See 37 C.F.R. § 1.104(a) concerning the Examiner's duty to consider and use any such information. Applicants respectfully request that the Examiner make the listed references of record in the file history of the application, and consider the information contained therein during the prosecution of this application.


Identification of the listed references is not to be construed an admission of any individual associated with the filing or prosecution of the subject application that such references are available as "prior art" against the subject application. Furthermore, Applicants

do not waive any rights to take appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the subject application.

Pursuant to 37 C.F.R. § 1.97(b), this Information Disclosure Statement is being filed before the mailing of a first Office Action on the merits. Accordingly, no fee is believed due. However, should the Patent Office determine otherwise, please charge the required fee to our Deposit Account No. 08-3425.

Dated: 9/9/03

Respectfully submitted,

By 
Melissa J. Pytel

Registration No.: 41,512
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(301) 610-5764

KKH/MJP/ba

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Jian Ni
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	4	Attorney Docket Number	PF400D1C1D1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A	US-5,965,421-B1	10-12-1999	Ni et al.	
	B	US-6,222,019-B1	04-24-2001	Ni et al.	
	C	US-5,654,397-B1	08-05-1997	Cao et al.	
	D	09/912,293	NOT PUBLISHED	Rosen, et al.	Pages 1-75 (pages 1 & 2 partially redacted); portion of Table 2; and SEQ ID NOS:5819, 29957, and 47106
	E	09/912,292	NOT PUBLISHED	Rosen, et al.	Pages 1-75 (pages 1 & 2 partially redacted); portion of Table 2; and SEQ ID NOS:557, 3821, 6645, and 6418

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	F	WO-94/17187-A1	08-04-1994	The Government of the United States of America		
	G	WO-97/00690-A1	01-09-1997	Tularik, Inc.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	H	Bergers et al., "Alternative promoter usage of the Fos-responsive gene Fit-1 generates mRNA isoforms coding for either secreted or membrane-bound proteins related to the IL-1 receptor," EMBO J. 13(5):1176-1188, Oxford University Press (1994).		
	I	Bird et al., "Evidence that MAP (Mitogen-Activated Protein) Kinase Activation May Be a Necessary but Not Sufficient Signal for a Restricted Subset of Responses in IL-1-Treated Epidermoid Cells," Cytokine 4(6):429-440, Academic Press (1992).		
	J	Bonnert et al., "The cloning and characterization of human MyD88: a member of an IL-1 receptor related family," FEBS Lett. 402(1):81-84, Elsevier (January 1997).		
	K	Cao et al., "IRAK: A Kinase Associated with the Interleukin-1 Receptor," Science 271:1128-1131, Association for the Advancement of Science (February 1996).		
	L	Cao et al., "TRAF6 is a signal transducer for interleukin-1," Nature 383:443-446, Macmillan Publishers Ltd. (October 1996).		
	M	Cleary et al., "Cloning and Structural Analysis of cDNAs for bcl-2 and a Hybrid bcl-2/Immunoglobulin Transcript Resulting from the t(14;18) Translocation," Cell 47:19-28, Cell Press (1986).		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Jian Ni
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	4	Attorney Docket Number	PF400D1C1D1

N	Eldon et al., "The Drosophila 18 wheeler is required for morphogenesis and has striking similarities to Toll," Development 120(4):885-899, The Company of Biologists Limited (1994).
O	Eriksson et al., "Biochemical Characterization of Type I IL-1 Receptor Associated Kinase (IRAK) Activities," Cytokine 7(6):649, Academic Press, Abstract A331 (1995).
P	Feinstein et al., "The death domain: a module shared by proteins with diverse cellular functions," Trends Biochem. Sci. 20:342-344, Elsevier Trends Journals (1995).
Q	Fleischmann et al., "Whole-Genome Random Sequencing and Assembly of Haemophilus influenzae Rd," Science 269:496-512, Association for the Advancement of Science (1995).
R	Galindo et al., "Interaction of the pelle kinase with the membrane-associated protein tube is required for transduction of the dorsoventral signal in Drosophila embryos," Development 121(7):2209-2218, The Company of Biologists Limited (1995).
S	Gay et al., "Drosophila Toll and IL-1 receptor," Nature 351:355-356, Macmillan Publishers Ltd. (1991).
T	Gayle et al., "Cloning of a Putative Ligand for the T1/ST2 Receptor," J. Biol. Chem. 271(10):5784-5789, American Society for Biochemistry and Molecular Biology, Inc. (March 1996).
U	Greenfeder et al., "Molecular Cloning and Characterization of a Second Subunit of the Interleukin 1 Receptor Complex," J. Biol. Chem. 270(23):13757-13765, American Society for Biochemistry and Molecular Biology, Inc. (1995).
V	Großhans et al., "Activation of the kinase Pelle by Tube in the dorsoventral signal transduction pathway of Drosophila embryo," Nature 372:563-566, Macmillan Publishers Ltd. (1994).
W	Hardiman et al., "Molecular characterization and modular analysis of human MyD88," Oncogene 13(11):2467-2475, Stockton Press (December 1996).
X	Hashimoto et al., "The Toll Gene of Drosophila, Required for Dorsal-Ventral Embryonic Polarity, Appears to Encode a Transmembrane Protein," Cell 52:269-279, Cell Press (1988).
Y	Hofmann et al., "The death domain motif found in Fas (Apo-1) and TNF receptor is present in proteins involved in apoptosis and axonal guidance," FEBS Lett. 371(3):321-323, Elsevier (1995).
Z	Hopp, T.P., "Evidence from sequence information that the interleukin-1 receptor is a transmembrane GTPase," Protein Science 4(9):1851-1859, Cambridge University Press (1995).
AA	Hultmark, D., "Macrophage Differentiation Marker MyD88 Is a Member of the Toll/IL-1 Receptor Family," Biochem. Biophys. Res. Commun. 199(1):144-146, Academic Press, Inc. (1994).
AB	Klemenz et al., "Serum- and oncoprotein-mediated induction of a gene with sequence similarity to the gene encoding carcinoembryonic antigen," Proc. Natl. Acad. Sci. USA 86(15):5708-5712, National Academy of Sciences of the USA (1989).
AC	Kumar et al., "ST2/T1 Protein Functionally Binds to Two Secreted Proteins from Balb/c 3T3 and Human Umbilical Vein Endothelial Cells but Does Not Bind Interleukin 1," J. Biol. Chem. 270(46):27905-27913, American Society for Biochemistry and Molecular Biology, Inc. (1995).
AD	Letsou et al., "Domain mapping of tube, a protein essential for dorsoventral patterning of the Drosophila embryo," EMBO J. 12(9):3449-3458, Oxford University Press (1993).
AE	Lord et al., "Nucleotide sequence and expression of a cDNA encoding MyD88, a novel myeloid differentiation primary response gene induced by IL6," Oncogene 5(7):1095-1097, Stockton Press (1990).
AF	Medzhitov et al., "A human homologue of the Drosophila Toll protein signals activation of adaptive immunity," Nature 388:394-397, Macmillan Publishers Ltd. (July 1997).
AG	Mitcham et al., "T1/ST2 Signaling Establishes It as a Member of an Expanding Interleukin-1 Receptor Family," J. Biol. Chem. 271(10):5777-5783, American Society for Biochemistry and Molecular Biology, Inc. (March 1996).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Jian Ni
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	3	of	4	Attorney Docket Number	PF400D1C1D1

AH	Muzio et al., "IRAK (Pelle) family member IRAK-2 and MyD88 as proximal mediators of IL-1 signaling," <i>Science</i> 278:1612-1615, Association for the Advancement of Science (1997).
AI	Norris et al., "Functional interactions between the pelle kinase, Toll receptor, and tube suggest a mechanism for activation of dorsal," <i>Genes Dev.</i> 10(7):862-872, Cold Spring Harbor Laboratory Press (April 1996).
AJ	Nomura et al., "Prediction of the Coding Sequences of Unidentified Human Genes. I. The Coding Sequences of 40 New Genes (KIAA0001-KIAA0040) Deduced by Analysis of Randomly Sampled cDNA Clones from Human Immature Myeloid Cell Line KG-1," <i>DNA Res.</i> 1:27-35, Universal Academy Press (1994).
AK	Ostrowski, et al., "A Serine/Threonine Kinase Activity Is Closely Associated with a 65-kDa Phosphoprotein Specifically Recognized by the κ B Enhancer Element," <i>J. Biol. Chem.</i> 266(19):12722-12733, American Society for Biochemistry and Molecular Biology, Inc. (1991).
AL	Parnet et al., "IL-1Rrp Is a Novel Receptor-like Molecule Similar to the Type I Interleukin-1 Receptor and Its Homologues T1/ST2 and IL-1R AcP," <i>J. Biol. Chem.</i> 271(8):3967-3970, American Society for Biochemistry and Molecular Biology, Inc. (February 1996).
AM	Reikerstorfer et al., "Low Affinity Binding of Interleukin-1 β and Intracellular Signaling via NF- κ B Identify Fit-1 as a Distant Member of the Interleukin-1 Receptor Family," <i>J. Biol. Chem.</i> 270(30):17645-17648, American Society for Biochemistry and Molecular Biology, Inc. (1995).
AN	Schneider et al., "Dominant and recessive mutations define functional domains of Toll, a transmembrane protein required for dorsal-ventral polarity in the Drosophila embryo," <i>Genes Dev.</i> 5:797-807, Cold Spring Harbor Laboratory Press (1991).
AO	Sims et al., "cDNA Expression Cloning of the IL-1 Receptor, a Member of the Immunoglobulin Superfamily," <i>Science</i> 241:585-589, Association for the Advancement of Science (1988).
AP	Sims et al., "Genomic Organization of the Type I and Type II IL-1 Receptors," <i>Cytokine</i> 7(6):483-490, Academic Press (1995).
AQ	Singh et al., "Cytosolic Domain of the Type I Interleukin-1 Receptor Spontaneously Recruits Signaling Molecules to Activate a Proinflammatory Gene," <i>J. Clin. Invest.</i> 100(2):419-428, The Rockefeller University Press (July 1997).
AR	Tominaga, S., "A putative protein of a growth specific cDNA from BALB/c-3T3 cells is highly similar to the extracellular portion of mouse interleukin 1 receptor," <i>FEBS Lett.</i> 258(2):301-304, Elsevier (1989).
AS	Yanagisawa et al., "Presence of a novel primary response gene ST2L, encoding a product highly similar to the interleukin 1 receptor type 1," <i>FEBS Lett.</i> 318(1):83-87, Elsevier (1993).
AT	GenBank Accession No. C05986, from Takeda, J. (October 1996).
AU	GenBank Accession No. W79504, from Hillier, L. et al. (October 1996).
AV	GenBank Accession No. AA171941, from Hillier, L. et al. (December 1996).
AW	GenBank Accession No. AA176605, from Hillier, L. et al. (December 1996).
AX	GenBank Accession No. N52479, from Hillier, L. et al. (January 1997).
AY	GenBank Accession No. AA368936, from Adams, M.D. et al. (April 1997).
AZ	GenBank Accession No. AA469327, from NCI-CGAP (August 1997).
BA	GenBank Accession No. AA557911, from NCI-CGAP (August 1997).
BB	GenBank Accession No. AA262752, from NCI-CGAP (August 1997).
BC	GenBank Accession No. AA491814, from NCI-CGAP (August 1997).
BD	GenBank Accession No. AA503258, from NCI-CGAP (August 1997).
BE	GenBank Accession No. AA528390, from NCI-CGAP (August 1997).
BF	GenBank Accession No. AA515224, from NCI-CGAP (August 1997).
BG	GenBank Accession No. AA482768, from NCI-CGAP (August 1997).
BH	GenBank Accession No. AA563770, from NCI-CGAP (September 1997).
BI	GenBank Accession No. AA582554, from NCI-CGAP (September 1997).
BJ	GenBank Accession No. AA583955, from NCI-CGAP (September 1997).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Jian Ni
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	4	of	4	Attorney Docket Number	PF400D1C1D1

	BK	GenBank Accession No. AA579566, from NCI-CGAP (September 1997).	
	BL	GenBank Accession No. AA579179, from NCI-CGAP (September 1997).	
	BM	GenBank Accession No. AA602557, from NCI-CGAP (September 1997).	
	BN	GenBank Accession No. AA587604, from NCI-CGAP (September 1997).	
	BO	GenBank Accession No. AA581903, from NCI-CGAP (September 1997).	
	BP	GenBank Accession No. AA584489, from NCI-CGAP (September 1997).	
	BQ	GenBank Accession No. AA613624, from NCI-CGAP (October 1997).	
	BR	GenBank Accession No. AA613627, from NCI-CGAP (October 1997).	
	BS	GenBank Accession No. AA640053, from NCI-CGAP (October 1997).	
	BT	GenBank Accession No. AA631497, from NCI-CGAP (October 1997).	
	BU	GenBank Accession No. AA527209, from NCI-CGAP (November 1997).	
	BV	GenBank Accession No. AA669840, from Jia, L. et al. (November 1997).	
	BW	GenBank Accession No. AA680243, from Hillier, L. et al. (December 1997).	
	BX	GenBank Accession No. AA610491, from NCI-CGAP (December 1997).	
	BY	GenBank Accession No. AA702605, from Hillier, L. et al. (December 1997).	
	BZ	GenBank Accession No. AA130647, from Hillier, L. et al. (December 1997).	
	CA	GenBank Accession No. AA714331, from NCI-CGAP (January 1998).	
	CB	GenBank Accession No. AA720702, from NCI-CGAP (January 1998).	
	CC	GenBank Accession No. AA779783, from Hillier, L. et al. (February 1998).	
	CD	GenBank Accession No. AA807583, from NCI-CGAP (February 1998).	
	CE	GenBank Accession No. AA805841, from NCI-CGAP (February 1998).	
	CF	GenBank Accession No. AA664604, from NCI-CGAP (February 1998).	
	CG	GenBank Accession No. AA665021, from NCI-CGAP (February 1998).	
	CH	GenBank Accession No. AA829085, from NCI-CGAP (February 1998).	
	CI	GenBank Accession No. AA846568, from NCI-CGAP (March 1998).	
	CJ	GenBank Accession No. AA653139, from Hillier, L. et al. (March 1998).	
	CK	GenBank Accession No. AA653612, from Hillier, L. et al. (March 1998).	
	CL	GenBank Accession No. AA608520, from Hillier, L. et al. (March 1998).	
	CM	GenBank Accession No. AA644090, from Hillier, L. et al. (March 1998).	
	CN	GenBank Accession No. AA876147, from NCI-CGAP (March 1998).	
	CO	GenBank Accession No. AA828676, from NCI-CGAP (April 1998).	
	CP	GenBank Accession No. AA828856, from NCI-CGAP (April 1998).	
	CQ	GenBank Accession No. AA904211, from NCI-CGAP (April 1998).	
	CR	Genbank Accession Nos. XO6364 and Y00696, from Witzmann (August 1993).	
	CS	GenBank Accession No. Z70280, from Burgess (March 1998).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--